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EXAMINER	
DAVIS, BRIAN J	

ART UNIT	PAPER NUMBER
1621	

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10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,136	LIM ET AL.	
	Examiner	Art Unit	
	Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8 and 10-13* is/are rejected.

7)☒ Claim(s) *1,6-9, 11 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: The period should come at the end of the claim (i.e. after the term H_2O). Claims must begin with a capital letter and end with a period. MPEP 608.01(m). Appropriate correction is required.

Claims 7-9, 11 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The method of claims 7-9, or the composition of claim 11, do not further limit the *compounds* of claim 1. Likewise, the method of claim 13 does not further limit the *composition* of claim 11.

Claim Rejections - 35 USC § 112, FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions containing compounds of Formula 1 and their method of use in the treatment of obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy, does not

reasonably provide enablement for *preventing* any of the above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With regard to rejections under 35 USC 112, first paragraph, the following factors are considered (*In re Wands* 8 USPQ 2d 1400, 1404 (CAFC 1988)): a) Breadth of claims; b) Nature of invention; c) State of the prior art; d) Level of ordinary skill in the art; e) Level of predictability in the art; f) Amount of direction and guidance provided by the inventor; g) Working examples and; h) Level of experimentation needed to make or use the invention based on the content of the disclosure.

a) The claims are quite broad: A pharmaceutical composition (claims 11 and 12) and a method (claim 13) for the treatment or prevention of obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy.

b,c) The nature of the invention is determined in part by the state of the prior art.

Even a cursory perusal of the teachings of the medicinal arts reveals that they have not advanced to the point where complex conditions such as obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy can be said to be preventable. The art, in general, teaches, instead, that what can be prevented with regard to such disorders are their associated symptoms, for example, seizure in the case of epilepsy.

d) The level of skill in the art is considered to be relatively high.

e) The level of predictability in the art is considered to be relatively low.

The basis of all modern medicine and biology is, of course, chemistry. Yet even under the best of circumstances, and several hundred years after Lavoisier laid the foundations of its modern practice, chemistry remains an experimental science. Neither the medicinal/biological arts nor the chemical arts upon which they are based have advanced to the point where certainty has replaced the need for clinical and/or laboratory experimentation.

f,g) The amount of direction provided by the inventor is considered to be determined by the specification and the working examples. Applicant's data do not demonstrate that the instant compounds prevent obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy.

h) Regardless of the amount of experimentation involved, applicant's claims to the prevention of the above disorders are not believable in light of the present understanding in the contemporary medicinal arts. It is settled case law that allegations of utility that are not believable in light of the contemporary knowledge in the art must be substantiated by acceptable evidence or stricken from the specification. In re Ferns, 163 USPQ 609 (CCPA 1969; Ex Parte Moore, 128, USPQ 8 (BPAI 1960); In re Hozumi, 226, USPQ 353 (Comr. Dec. 1985); MPEP 706.03(n) and 706.03(z).

Claim Rejections - 35 USC § 112, SECOND PARAGRAPH

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The exact meaning of the term "related disorders" is unclear because it is undefined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by BR 2001005486 (CAPLUS abstract). The reference teaches applicant's sulfate salt: RN=732275-42-2. Claims 2-4 are included in this rejection because the X-ray diffraction data is intrinsic the salt. That is, it is a property of the salt. A compound and its properties are inseparable. *In re Papesch*, 315, F.2d 381, 137 USPQ 43 (CCPA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over BR 2001005486 above.

Applicant claims a method of preparation of the sulfate salt of sibutramine (i.e. an acid addition salt).

BR 2001005486 teaches this salt: RN=732275-42-2.

Applicant distinguishes over the prior art in that the step of adding the acid to sibutramine to form the acid addition salt is explicitly taught. However, one of ordinary skill in the art at the time of the invention would have immediately recognized, given the prior art acid addition salt, that an acid addition salt –any acid addition salt – is routinely formed by adding an acid to an amine either neat or in an appropriate solvent.

Claims 1, 5, 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2184122 (CAPLUS abstract) and applicant's admission in the specification (page 2, line 15).

Applicant claims the Br acid addition salt of sibutramine, its method of making and its pharmaceutical compositions and use.

GB 2184122 teaches the Cl monohydrate acid addition salt of sibutramine in the treatment of depression.

Applicant explicitly admits in the specification that many acid addition salts of sibutramine are known, in particular the Cl salt. Applicant also admits that the Cl salt is difficult to handle due to it hygroscopic nature.

Applicant principally distinguishes over the prior art in that the Br acid addition salt of sibutramine is explicitly taught. However, one of ordinary skill in the art at the time of the invention would have been motivated to search for further acid addition salts of sibutramine given the known handing difficulties of the Cl salt. Furthermore, given the art's preference for the Cl salt, one of ordinary skill would have been motivated to search for these other salts among the halogen acid addition salts. Bromine is the next halogen in the Periodic Table of the Elements and therefore the next logical choice to try. Finally, given the success of the Cl salts in pharmaceutical compositions and methods of their use, the reasonable expectation exists for a similar success with the analogous Br salt.

Allowable Subject Matter

Claims 6 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
September 28, 2007